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(54) Title: **APPARATUS AND METHOD FOR ADVANCING COOLING CATHETER**

(57) Abstract: A cooling catheter is advanced through the femoral vein of a patient into the vena cava for therapeutic or prophylactic cooling of a patient by first sliding a peel-away protector sheath down the catheter until it covers and constrains a distal heat exchange element, such as plural hollow fibers through which coolant flows. An introducer sheath is advanced into the femoral vein, and then the protector sheath with heat exchange element therein is advanced into the introducer sheath. The protector sheath is then peeled away and removed from the catheter, and the catheter can be advanced as desired through the introducer sheath. When desired, the introducer sheath can be removed from the patient by peeling away the sheath from the catheter.

APPARATUS AND METHOD FOR ADVANCING COOLING CATHETER
RELATED APPLICATION

This is a continuing application of co-pending U.S. patent application serial no. 09/294,080, filed April 19, 1999, which claims priority from of co-pending U.S. patent application serial no. 09/133,813, filed August 13, 1998, from which priority is claimed.

FIELD OF THE INVENTION

The present invention relates generally to catheters for cooling patients for therapeutic purposes.

BACKGROUND

It has been discovered that the medical outcome for a patient suffering from severe brain trauma or from ischemia caused by stroke or heart attack is degraded if the patient's body temperature rises above normal (38°C). It is further believed that the medical outcome for many such patients might be significantly improved if the patients were to be quickly brought down in temperature and maintained in a mildly hypothermic state for a short period, e.g., 24-72 hours. Moreover, prophylactic short-term hypothermia might help patients undergoing minimally invasive heart surgery and aneurysm surgery.

The affected organ, in any case, is the brain. Accordingly, systems and methods have been disclosed that propose cooling blood flowing to the brain through the carotid artery. An example of such systems and methods is disclosed in co-pending U.S. pat. app.

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serial no. 09/063,984, filed April 21, 1998, owned by the present assignee and incorporated herein by reference. In the referenced application, various catheters are disclosed which can be advanced into a patient's carotid artery and through which coolant can be pumped in a closed circuit, to remove heat from the blood in the carotid artery and thereby cool the brain. The referenced devices have the advantage over other methods of cooling (e.g., wrapping patients in cold blankets) of being controllable, relatively easy to use, and of being capable of rapidly cooling and maintaining blood temperature at a desired set point.

As recognized in the parent U.S. pat. app. serial nos. 09/133,813 and 09/294,080, both of which are incorporated herein by reference, the above-mentioned advantages in treating brain trauma/ischemic patients by cooling can also be realized by cooling the patient's entire body, i.e., by inducing systemic hypothermia. The advantage of systemic hypothermia is that, as recognized by the present assignee, to induce systemic hypothermia a cooling catheter or other cooling device need not be advanced into the blood supply of the brain, but rather can be easily and quickly placed into the relatively large vena cava of the central venous system.

One path for advancing the above-referenced catheters into the vena cava is through the femoral vein. An incision can be made in the femoral vein and then the catheter advanced through the incision, up the femoral vein, and into the vena cava, where it can advantageously be used to cool the patient. As described in U.S. patent application serial no. 09/294,080, coolant can be pumped through looped hollow fibers at the distal end of the catheter to effect the cooling. Owing to their axial flexibility, however, the hollow fibers cannot simply be advanced directly into the vena cava, but must be inserted using additional

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structure. The present invention is directed to methods and apparatus for undertaking this insertion.

SUMMARY OF THE INVENTION

A kit for positioning a catheter including a distal heat exchange element in a vessel of a patient includes the catheter and a protector sheath that is slidably engageable with the catheter. The protector sheath is movable between a proximal position, wherein the heat exchange element is exposed, and a distal position, wherein the heat exchange element is constrained within the protector sheath. An introducer sheath is positionable in a patient and is configured for receiving the protector sheath therein, it being understood that the protector sheath thus constrains the heat exchange element to facilitate disposing the heat exchange element within the introducer sheath. In accordance with the present invention, the protector sheath can be removed from the catheter, e.g., by peeling away the sheath, when the heat exchange element is within the introducer sheath. The catheter can then be advanced through the introducer sheath toward the vessel. In preferred embodiments, the heat exchange element can include at least one hollow fiber configured for carrying coolant.

In another aspect, a method of advancing a heat exchange element of a catheter into a patient includes engaging the catheter with a sheath, and using the sheath to advance at least the heat exchange element into the patient.

In still another aspect, a kit for therapeutic or prophylactic hypothermia includes at least a first sheath and at least one catheter including a heat exchange element. At least the heat exchange element is engageable with the first sheath to facilitate advancing the

heat exchange element into a patient.

The details of the present invention, both as to its structure and operation, can best be understood in reference to the accompanying drawings, in which like reference numerals refer to like parts, and in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of the present cooling catheter with the heat exchange element protector sheath in the fully proximal position and the heat exchange element exposed, with portions broken away;

Figure 2 is a side elevational view of the present cooling catheter with the heat exchange element protector sheath in the fully distal position, covering the heat exchange element, in an exploded relationship with the introducer sheath, with the introducer sheath shown advanced into the femoral vein of a patient, with portions broken away;

Figure 3 is a side elevational view of the present cooling catheter with the heat exchange element protector sheath in the introducer sheath within the patient and partially peeled away from the catheter, with portions broken away; and

Figure 4 is a side elevational view of the present cooling catheter with the introducer sheath partially peeled away prior to removing the introducer sheath.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring initially to Figure 1, a therapeutic catheter system, generally designated 10, is shown for establishing and maintaining hypothermia in a patient, or for attenuating

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a fever spike in a patient and then maintaining normal body temperature in the patient. The catheter system 10 includes a catheter 12 through which coolant is circulated in a closed loop to and from a heat exchange element 14. The details of the preferred catheter 12 and preferred hollow fiber heat exchange element 14 are set forth in the above-referenced parent applications, and will not be repeated here. The coolant that flows through the catheter 12 and heat exchange element 14 is returned to a cooler, such as either of the systems disclosed in co-pending U.S. patent application serial no. 09/220,897, filed December 24, 1998 and incorporated herein by reference, or U.S. patent application serial no. 09/260,950, filed March 2, 1999, also incorporated herein by reference. In any case, the cooler provides coolant such as saline to the heat exchange element 14.

The preferred heat exchange element 14 includes plural hollow fibers 16, preferably seven fibers each configured in a loop. Other heat exchange elements can be used, such as balloons, or bellows-type structures.

An elongated hollow plastic protector sheath 18 is slidably engageable with the catheter 12 and is movable between a proximal position shown in Figure 1, wherein the heat exchange element 14 is exposed, and a distal position shown in Figure 2, wherein the heat exchange element 14 is constrained within the protector sheath 18. In one preferred embodiment, the protector sheath 18 is an Angetear® sheath made by B. Braun Medical, Inc. of Bethlehem, PA. Accordingly, the protector sheath 18 includes a frangible tab 20 having opposed ears 22 that can be grasped by a person and pulled apart to longitudinally separate the sheath 18 into two pieces. The purpose of the

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protector sheath 18 is to facilitate disposing the heat exchange element 14 within an introducer sheath by constraining the heat exchange element.

Accordingly, as shown in Figures 2 and 3 an introducer sheath 24 is positionable in a patient 26 and is configured for receiving the protector sheath 18. In the preferred embodiment the introducer sheath 24 is identical in construction to the protector sheath 18, except that the introducer sheath 24 can be marginally longer than the protector sheath 18, e.g., 30 cm versus 25 cm. Accordingly, the introducer sheath 24 is also a peel-away sheath. It is to be understood that the introducer sheath 24 is advanceable into the patient 26 over a dilator and guidewire in accordance with percutaneous insertion principles known in the art.

In operation, the introducer sheath 24 is first advanced into the patient 26 to the position shown in Figures 2 and 3. Then, the protector sheath 18 is moved to the distal position, and the protector sheath 18 with catheter 12 inserted into the introducer sheath 24 as shown in Figure 3. As can be appreciated in reference to Figure 3, the protector sheath 18 is removed from the catheter 12 by peeling away the protector sheath 18 when the heat exchange element 14 is within the introducer sheath 24. With the introducer sheath 24 then constraining the heat exchange element 14, the catheter 12 can be advanced through the introducer sheath 24 toward a vessel, e.g., the inferior vena cava. Once the catheter 12 is positioned appropriately, the introducer sheath 24 is peeled away and removed as can be appreciated in reference to Figure 4. I have discovered that advantageously, neither of the preferred sheaths crimps the bights of the looped fibers that establish the preferred heat exchange element 14. Indeed, coolant can be pumped

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through the fibers while the fibers are being engaged with the sheaths.

While the particular APPARATUS AND METHOD FOR ADVANCING COOLING CATHETER as herein shown and described in detail is fully capable of attaining the above-described objects of the invention, it is to be understood that it is the presently preferred embodiment of the present invention and is thus representative of the subject matter which is broadly contemplated by the present invention, that the scope of the present invention fully encompasses other embodiments which may become obvious to those skilled in the art, and that the scope of the present invention is accordingly to be limited by nothing other than the appended claims, in which reference to an element in the singular is not intended to mean "one and only one" unless explicitly so stated, but rather "one or more". All structural and functional equivalents to the elements of the above-described preferred embodiment that are known or later come to be known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the present claims. Moreover, it is not necessary for a device or method to address each and every problem sought to be solved by the present invention, for it to be encompassed by the present claims. Furthermore, no element, component, or method step in the present disclosure is intended to be dedicated to the public regardless of whether the element, component, or method step is explicitly recited in the claims. No claim element herein is to be construed under the provisions of 35 U.S.C. 112, sixth paragraph, unless the element is expressly recited using the phrase "means for".

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WHAT IS CLAIMED IS:

1. A kit for positioning a catheter including a distal heat exchange element in a vessel of a patient, comprising:
the catheter;
a protector sheath slidably engageable with the catheter and movable between a proximal position, wherein the heat exchange element is exposed, and a distal position, wherein the heat exchange element is constrained within the protector sheath; and
an introducer sheath positionable in a patient and configured for cooperation with the protector sheath, the protector sheath being removable from the catheter when the heat exchange element is within the introducer sheath, the catheter being advanceable through the introducer sheath toward the vessel.
2. The kit of Claim 1, wherein at least one of the sheaths is a peel away sheath.
3. The kit of Claim 2, wherein the heat exchange element includes at least one hollow fiber configured for carrying coolant.
4. The kit of Claim 2, wherein at least one of the sheaths includes at least one tab for grasping thereof to separate the sheath longitudinally.
5. A method of advancing a heat exchange element of a catheter into a patient, comprising the acts of:
engaging the catheter with a sheath; and

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- using the sheath to advance at least the heat exchange element into the patient.
6. The method of Claim 5, wherein the sheath is a protector sheath, and the method includes the acts of:
- Prior to advancing the heat exchange element into the patient, slidably engaging the protector sheath with the catheter to constrain the heat exchange element in the protector sheath.
7. The method of Claim 6, wherein the method further comprises the acts of:
- providing an introducer sheath;
- advancing the introducer sheath into a patient;
- advancing the protector sheath into the introducer sheath to thereby dispose the heat exchange element in the patient.
8. The method of Claim 7, wherein the method further comprises the acts of:
- peeling away one or both sheaths from the catheter.
9. The method of Claim 5, wherein the sheath is an introducer sheath, and the method further comprises the acts of:
- providing a protector sheath;
- prior to advancing the heat exchange element into the patient, slidably engaging the protector sheath with the catheter to constrain the heat exchange element in the protector sheath; then
- advancing the protector sheath into the introducer sheath.

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10. A kit for therapeutic or prophylactic hypothermia, comprising:
 - at least a first sheath; and
 - at least one catheter including a heat exchange element, at least the heat exchange element being engageable with the first sheath to facilitate advancing the heat exchange element into a patient.
11. The kit of Claim 10, further comprising a second sheath, one of the sheaths constraining the heat exchange element and the other sheath establishing an introducer pathway into the patient.
12. The kit of Claim 11, wherein at least one of the sheaths is a peel away sheath.
13. The kit of Claim 12, wherein the heat exchange element is established by at least one coolant-bearing hollow fiber.
14. An apparatus for inducing hypothermia in a patient, comprising:
 - heat exchanger means for exchanging heat with the patient;
 - catheter means for carrying coolant to and from the heat exchanger means; and
 - sheath means for facilitating advancing the heat exchanger means into the patient.

